

## REMARKS

According to the Notice of Non-Compliant Amendment dated January 7, 2009, the listing of claims in Applicant's submission dated October 10, 2008, included incorrect claim identifiers. Please disregard the submission dated October 10, 2008, and instead enter claims 1-3, 5-15 and 17-86 as set forth in the claim listing provided herewith.

Claims 1-3, 5-15 and 17-86 are pending and under examination. Claims 29-62 and 77-84 have been canceled. Claims 1, 15, 24-28, 63, 64, 85 and 86 have been amended to delete the term "synovium." Claims 9-14 and 71-76 have been amended to clarify the claim scope with fgreater particularity. The amendments do not introduce any new matter and entry of the amendments is respectfully requested. Upon entry of the amendments, claims 1-3, 5-15, 17-28, 63-76, 85 and 86 will be pending and under consideration.

### Regarding 35 U.S.C. §112, First Paragraph

The objection to the specification and corresponding rejection of claims 1-3, 5-15, 17-28, 63-76, 85 and 86 under 35 U. C. 112 , first paragraph, for allegedly lacking an enabling disclosure is respectfully rejected.

The Office Action, beginning at page 5, asserts that Applicants arguments in the previous response are unpersuasive. Briefly, Applicants argued firstly that the Simko and Mattson reference confirms that *in vitro* results are accepted in the art as reasonably correlating to *in vivo* results by using the *in vitro* data regarding cellular changes in response to electromagnetic field exposure as a basis to draw a variety of conclusion about *in vivo* effects and should be accepted as evidence for the enablement of the *in vivo* embodiments of the invention. Secondly, Applicants argued and provided legal authority for the proposition that that as long as it is routine, even a significant amount of experimentation doe not defeat enablement. *Johns Hopkins Univ. v. CellPro, Inc.*, 152 F.3d 1342, 47 U.S.P.Q.2d 1705 (Fed. Cir. 1998). Applicants respectfully requested that the Office produce particular evidence why the *in vitro* methods are unacceptable as evidence for the enablement of the *in vivo* embodiments of the invention. Rather than providing a rebuttal of Applicants' arguments, the Examiner now reiterates that enablement is based on evaluation of a combination of factors including scope of the claims, state of the art, unpredictability of the art, amount of guidance provided , working examples, nature of the

invention and level of skill in the art. It is again alleged that the scope of the claimed methods is very broad, the methods are not routine, there are art recognized issues in delivering electromagnetic energy to an *in vivo* complex tissue and the working examples and guidance provided by the specification do not provide a sufficient basis for the skilled artisan to be able to make or use this invention without undue trial and error experimentation. The Examiner does not appear to rebut, but clearly discounts the impact of the fact that *in vitro* results are accepted in the art as reasonably correlating to *in vivo*. A general allegation that methods of this kind are not routine and are known in the art to be unpredictable is not a sufficient basis to maintain the instant enablement rejection in view of the extensive teachings and working examples as previously discussed on the record; the Office's acknowledgement that the *in vitro* methods are enabled and the evidence those skilled in the art accepted the correlation between *in vitro* and *in vivo* results for the claimed methods. It is respectfully maintained that the enablement rejection is not properly supported.

Accordingly, Applicants respectfully request withdrawal of the objection to the specification and removal of the corresponding rejection of claims 1-3, 5-15, 17-28, 63-76, 85 and 86 under 35 U. C. 112, first paragraph, for allegedly lacking an enabling disclosure.

#### **Regarding 35 U.S.C. § 102**

When lack of novelty is based on a printed publication that is asserted to describe the same invention, a finding of anticipation requires that the publication describe all of the elements of the claims. *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1349, 48 U.S.P.Q.2d 1225, (Fed. Cir. 1998) (quoting *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544-45, 24 U.S.P.Q.2d 1133, 1136 (Fed. Cir. 1992)). To establish a *prima facie* case of anticipation, the Office must show that the single reference cited as anticipatory art describes all the elements of the claimed invention.

The rejection of claims 1-3, 5-8, 15, 17-23, 63-70 and 85-86 under 35 U.S.C. §102(b) as being anticipated by Gordon et al (U. S. Patent No. 4,758,429) is respectfully traversed. Without conceding that there is any merit to the instant rejection, Applicants submit that the rejection is rendered moot by the amendments to the claims proposed above. Accordingly, removal of the rejection is respectfully requested.

**Regarding 35 U.S.C. § 112, Second Paragraph**

Applicants respectfully traverse the rejection of claims 9-14 and 71-76 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Applicants submit that, when viewed in light of the specification of which they are part, claims 9-14 and 21-26 are sufficiently clear and definite to the skilled person to comply with the second paragraph of section 112 of the Code. Nevertheless, Applicants have amended claims 9-14 and 21-26 to clarify the claimed scope, thereby addressing and rendering moot the instant rejection. Accordingly, Applicants respectfully request removal of the rejection of claims 9-14 and 71-76 under 35 U.S.C. §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

**CONCLUSION**

In light of the amendments and remarks herein, Applicants submit that the claims are now in condition for allowance and respectfully request a notice to this effect. The Examiner is invited to call the undersigned attorney if there are any questions.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 502624 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP

/Astrid R. Spain/

Astrid R. Spain  
Registration No. 47,956

**Please recognize our Customer No. 41552  
as our correspondence address.**

11682 El Camino Real, Suite 400  
San Diego, CA 92130  
Phone: 858.720.3300 ARS:cjh  
Facsimile: 858.720.7800  
**Date: February 9, 2009**